AUG 0 3 2006

IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF TEXAS HOUSTON DIVISION

Michael N. Milby, Clark

UNITED STATES OF AMERICA

Plaintiff.

§ § -272

18 U.S.C. § 2320(a)

FAYEZ ALEDOUS

v.

§ § 21 U.S.C. § 331(a) 21 U.S.C. § 331(I)

Defendant.

INDICTMENT

THE GRAND JURY CHARGES:

A. INTRODUCTION

At all times material to this indictment:

- The United States Food and Drug Administration (FDA) is the agency of the United States charged with the responsibility of protecting the health and safety of the American public by ensuring, among other things, that drugs sold for administration to humans bear labeling containing true and accurate information. The FDA's responsibilities include regulating the labeling and distributing of prescription drugs shipped or received in interstate commerce.
- 2. Under the Food Drug and Cosmetic Act, the definition of a "drug" includes articles which (1) are intended for use in the diagnoses, cure, mitigation, treatment or prevention of disease in man, and (2) are intended to affect the structure or function of the body of man. Due to the toxicity and other potential harmful effect, certain drugs are not considered safe for use except for use under the supervision of a practitioner licensed by law to administer such drugs. These drugs are known as prescription drugs.
 - Viagra was a prescription drug product that had been approved by the FDA for

distribution within the United States.

- Pfizer Pharmaceuticals (Pfizer) had the exclusive right to manufacture Viagra for distribution within the United States.
- The name "Viagra" was a trademark owned by Pfizer and is registered in the principal registry in the United States Patent and Trademark Office.
- Cialis was a prescription drug product that had been approved by the FDA for 6. distribution within the United States.
- Eli Lilly Corporation (Eli Lilly) had the exclusive right to manufacture Cialis for 7. distribution within the United States.
- The name "Cialis" was a trademark owned by Eli Lilly and is registered in the principal registry in the United States Patent and Trademark Office.
- The Food Drug and Cosmetic Act also regulates the importation, delivery, distribution and receipt of prescription drugs in interstate commerce. Under the Act, a prescription drug is deemed misbranded if its labeling is false or misleading in any particular manner. A prescription drug is also deemed to be counterfeit if it bears a trademark without the authorization of the registrant of the trademark.
- 10. Fayez Aledous, a defendant herein, operates R U SOPHISTICATED, a retail outlet located at 6820 Harwin Drive, Houston, Texas that sells handbags and accessories.

COUNT ONE (Misbranded Drugs)

1. On or about July 6, 2006, in the Houston Division of the Southern District of Texas, the defendant,

FAYEZ ALEDOUS

with the intent to defraud and mislead, caused the introduction and delivery for introduction into interstate commerce drugs that were misbranded, namely that a shipment containing bottles of counterfeit Viagra pills were labeled in a manner to falsely represent that the bottles contained the genuine Viagra pharmaceutical drug.

In violation of Title 21, United States Code, Sections 331(a) and 333(a)(2).

COUNT TWO (Misbranded Drugs)

1. On or about July 6, 2006, in the Houston Division of the Southern District of Texas, the defendant,

FAYEZ ALEDOUS

with the intent to defraud and mislead, caused the introduction and delivery for introduction into interstate commerce drugs that were misbranded, namely that a shipment containing bottles of counterfeit Cialis pills were labeled in a manner to falsely represent that the bottles contained the genuine Cialis pharmaceutical drug.

In violation of Title 21, United States Code, Sections 331(a) and 333(a)(2).

COUNT THREE (Counterfeit Drugs)

1. On or about July 6, 2006, in the Houston Division of the Southern District of Texas, the defendant,

FAYEZ ALEDOUS

with the intent to defraud and mislead, caused bottles containing counterfeit Viagra to be labeled with the trademark Viagra without the authorization and permission of Pfizer Pharmaceuticals, the registered holder of said trademark.

In violation of Title 21 United States Code, Sections 331(i) and 333(a)(2).

COUNT FOUR (Counterfeit Drugs)

1. On or about July 6, 2006, in the Houston Division of the Southern District of Texas, the defendant,

FAYEZ ALEDOUS

with the intent to defraud and mislead, caused bottles containing counterfeit Cialis to be labeled with the trademark Cialis without the authorization and permission of Eli Lilly Corporation, the registered holder of said trademark.

In violation of Title 21 United States Code, Sections 331(i) and 333(a)(2).

COUNT FIVE (Trafficking in Counterfeit Goods)

1. On or about July 6, 2006, in the Houston Division of the Southern District of Texas, the defendant,

FAYEZ ALEDOUS

aided and abetted by others unknown to the Grand Jury, did intentionally traffic and attempt to traffic in goods, namely, pharmaceutical drugs, and knowingly used a counterfeit mark on and in connection with such goods, that is, the Viagra trademark used to identify a pharmaceutical product marked by Pfizer Pharmaceuticals, which counterfeit mark was identical with and substantially indistinguishable from the genuine mark in use and registered for that good on the principle register in the United States Patent and Trademark Office, and the use of which mark was likely to cause confusion, mistake and deception regarding said mark.

In violation of Title 18, United States Code, Section 2320(a).

COUNT SIX (Trafficking in Counterfeit Goods)

1. On or about July 6, 2006, in the Houston Division of the Southern District of Texas, the defendant,

FAYEZ ALEDOUS

aided and abetted by others unknown to the Grand Jury, did intentionally traffic and attempt to traffic in goods, namely, pharmaceutical drugs, and knowingly used a counterfeit mark on and in connection with such goods, that is, the Cialis trademark used to identify a pharmaceutical

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product marked by Eli Lilly Corporation, which counterfeit mark was identical with and substantially indistinguishable from the genuine mark in use and registered for that good on the principle register in the United States Patent and Trademark Office, and the use of which mark was likely to cause confusion, mistake and deception regarding said mark.

In violation of Title 18, United States Code, Section 2320(a).

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ORIGINAL SIGNATURE ON FILE WITH THE CLERK

DONALD J. DeGABRIELLE, JR. UNITED STATES ATTORNEY

Samuel J. Louis

Assistant United States Attorney